UNITED STATES PATENT AND TRADEMARK OFFICE

UNITED STATES DEPARTMENT OF COMMERCE
United States Patent and Trademark Office
Address: COMMISSIONER FOR PATENTS
P.O. Box 1450
Alexandria, Virginia 22313-1450
www.uspto.gov

APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/751,152	01/02/2004	Rod Lawson Hartwig	NOPH/112/JGK	5442

7590 03/05/2007

Noven Pharmaceuticals, Inc.
Jay G. Kolman, Esq.
11960 S.W. 144 Street
Miami, FL 33186

EXAMINER	
MERCIER, MELISSA S	
ART UNIT	PAPER NUMBER
1615	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
3 MONTHS	03/05/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/751,152	HARTWIG, ROD LAWSON	
	Examiner	Art Unit	
	Melissa S. Mercier	1615	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☐ Responsive to communication(s) filed on _____.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *1-18* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

> (a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negatived by the manner in which the invention was made.

The factual inquiries set forth in *Graham* **v.** *John Deere Co.*, 383 U.S. 1, 148 USPQ 459 (1966), that are applied for establishing a background for determining obviousness under 35 U.S.C. 103(a) are summarized as follows:

1. Determining the scope and contents of the prior art.
2. Ascertaining the differences between the prior art and the claims at issue.
3. Resolving the level of ordinary skill in the pertinent art.
4. Considering objective evidence present in the application indicating obviousness or nonobviousness.

Claims 1-17 rejected under 35 U.S.C. 103(a) as being unpatentable over Grohe (US Patent 4,844,902) in view of Jain et al (US Patent 5,780,050).

The claims are drawn to a transdermal formulation comprising a therapeutically effective amount of one or more active agents, a pharmaceutically acceptable carrier, and a rosin ester. The rosin ester is recited to be a pentaerythritol ester. The carrier substance includes a polyacrylate polymer and a polyvinylpyrrolidone as an enhancer. The claims further recite that the active substance, though not critical, is recited to be selected from the group of testosterone and methyltestosterone.

Grohe teaches a transdermal formulation for the delivery of active agents comprising polyvinylpyrrolidone and polyacrylate in the gel layer. The composition further comprises resins, specifically pentaerythritol esters of hydrogenated rosin (Abstract; column 4, lines 21 - 26; column 8, lines 28 - 35).

Grohe does not disclose the resin in the gel layer. Grohe discloses as a possible constituent, a pentaerythritol ester of hydrogenated rosin, while applicant claims non-hydrogenated rosin. Yet applicant has no antecedent basis for a non-hydrogenated rosin, only a partially and fully hydrogenated rosins, which are both disclosed by Grohe. Also with regard to the rosin resins, applicant recites that the resin is present in an amount up o 25% by weight of tile total composition. Grohe is silent to the specific concentration yet, teaches the general presence of the rosin esters, particularly a pentaerythritol ester. Where the general conditions of a claim are disclosed in the prior art, it is not inventive to discover the optimum or workable ranges by routine experimentation. In re Aller, 220 F.2d 454 105 USPQ 233,235 (CCPA 1955).

The Grohe reference is silent to the inclusion of an additional adhesive polymer, specifically a polysiloxane. Applicant claims a combination of adhesive polymers, yet the reference claims a singular polymer. Though not critical to applicant's invention, Grohe is deficient in its disclosures of its active ingredients. Grohe teaches transdermal formulations with a different class of steroid compounds than applicant, corticosteroids. These compounds are applicable to treat infections and disease and are ready additives to many transdermal formulations.

Jain et al teaches a transdermal delivery system, comprising flexible backing, and a gel layer. The gel layer of Jain comprises both acrylic polymers and polysiloxanes. The reference further discloses the presence of polyvinylpyrrolidones as active enhancer. The active ingredients in the formulations of Jain are corticosteroids and sex hormones such as progestins and androgens. Included in these androgens are testosterone and methyltestosterone (Abstract; column 4, line 56 through column 5, line 14; column 6, lines 16 - 24; claims).

Though Jain too discloses elements of the claimed invention, the claims differ from the reference by reciting various concentrations of adhesive polymers. However, the preparations of various transdermal compositions having various amounts of the adhesive polymers is within the level of skill of one having ordinary skill in the art at the time of the invention. It has also been held that the mere selection of proportions and ranges is not patentable absent a showing of criticality. In re Russell, 439 F.2d 1228, 169 USPQ 426 (CCPA 1971).

With regard to claims 1 and 9, applicant claims that the formulations are free of 1-methol and can deliver their active agents in a period over 24 hours. Both references are silent to the presence of any 1-menthols and to the time at which they can deliver their active ingredients. However this delivery time is dependent upon the choice of polymers, and concentrations, which can be determined by one of ordinary skill in the art through routine experimentation.

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to combine the teachings of Grohe and Jain. A skilled

artisan would be motivated to combine the resins suggested by Grohe into the active layer Jain in order to improve the adhesive properties of the formulation. It would have been obvious to one of ordinary skill in the art, at the time of the invention to combine the teachings in this way with the expected result of a more adhesive transdermal formulation free of 1-methol and able to deliver steroids to a patient in need thereof.

Claim 18 is rejected under 35 U.S.C. 103(a) as being unpatentable over Grohe (US Patent 4,844,902)) in view of Jain et al (US Patent 5,780,050 and further in view of Effing et al (US Patent 5,702,720) and Nuwayser (US Patent 4,624,665).

The claim is drawn to a method of producing a transdermal formulation comprising making a blend of active agents, carrier composition and a rosin ester resin. The blend is made into a pressure sensitive adhesive patch and then dried to remove solvents.

The combination of Jain and Grohe are discussed above and applied in the same manner.

Jain further teaches a method of making the formulation where a mixture is made of the active ingredients and the carrier composition. This mixture is formed into a pressure-sensitive patch and it is further processed by known methods in the art (column 9, lines 1- 13).

The references are silent to a specific drying step in order to remove solvents yet, the removal of solvents is known in the art. This removal of solvents removes residual monomers (Effing), which improves the shelf life of a polymeric product and

provides a dry composite formulation with a uniform distribution of active agents (Nuwayser).

Therefore, it would have been obvious to a person of ordinary skill in the art at the time the invention was made to follow the suggestion made by Jain and follow the knowledge in the art. A skilled artisan would have been motivated to remove the solvents of combination of Jain and Grohe, by known means in the art, in order to provide a more uniform distribution of active agents. It would have been obvious to one of ordinary skill in the art, at the time of the invention to follow the suggestions provided by Jain and the knowledge in the art with an expected result of a pressure sensitive-adhesive transdermal delivery system with a uniform distribution of its active agents, and reduced residual monomers and better shelf life.

Conclusion

No claims are allowable. Any inquiry concerning this communication or earlier communications from the examiner should be directed to Melissa S. Mercier whose telephone number is (571) 272-9039. The examiner can normally be reached on 7:30am-4pm Mon through Friday.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Michael Woodward can be reached on (571) 272-8373. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

MSMercier

Gollamudi S. Kishore, PhD
Primary Examiner
Group 1500